

REMARKS

Claim 1 has been amended to obviate rejections under 35 U.S.C. § 112, paragraph 2, and to distinguish the claimed rodent from that described in the document cited below. Support for this amendment is found in paragraph 12 of the specification on page 3 and in paragraphs 46-48 of the specification on claims 10-11. Thus, no new matter has been added and entry of the amendment is respectfully requested.

It is believed that the amendment is completely responsive to the rejection under 35 U.S.C. § 112, paragraph 2. The word “first” has been deleted, and the term “essentially” has been explained as set forth in paragraph 46 on page 10.

It is further believed that the rejection for anticipation by Kern (WO 02/28188) is obviated by this amendment.

Kern is a prophetic disclosure of how one might prepare a transgenic mouse that expresses green fluorescent protein. According to the prophecy of Kern, this mouse is prepared by integrating a detectable gene into the chromosome of a mouse embryonic stem cell and using the embryonic stem cell to develop strains of homozygous mice having two copies of the integrated construct in every cell and then breeding the resulting mice with *nu/nu* mice to produce mice that are homozygous for a transgene and homozygous for immunodeficiency, as pointed out by the Examiner.

As the disclosure of Kern is prophetic, it is difficult to determine exactly the genetic makeup of the mice, but it is clear that it must be different from the genetic makeup of the mice as now claimed. As noted in the claim, the rodents included in the claim ultimately result from a “fourth” cross between a mouse that expresses fluorescent protein and is immunocompromised with a mouse that is merely immunocompromised and not modified to produce fluorescent protein. It is this

innovation that results in the maintenance of immunodeficiency even though the fluorescent protein is produced. Respectfully, it is believed that Kern cannot be said to disclose inherently the specific type of rodent now claimed. Clearly the specific type of rodent now claimed would not inevitably result from the rather vague description provided by Kern.

In order to show anticipation, an undisclosed property cannot be established by probabilities or possibilities, but must be established with certainty. *In re Robertson*, 169 F3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). The *Robertson* case is about disposable diapers. The claim at issue provided for two mechanical fastening means to attach the diaper to the wearer and a third means for securing the diaper for disposal. The cited reference did not disclose a separate fastener, but the Board had found that the third fastening element could be inherent in the cited disclosure because it would have been possible to attach the first and second fastening elements to each other, thus forming the third element. Indeed, the claim at issue did not specifically require a “separate” third fastening means. In reversing a finding of any inherent anticipation, the majority said:

To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be recognized by persons of ordinary skill.”

Citing *Continental Can Co. v. Monsanto Co.* (supra), 948 F2d 1264, 1268, 20 USPQ2d 1746 (Fed. Cir. 1991).

Thus, in accordance with the holding in *Robertson*, without evidence of record that the mice prepared by Kern are identical to those claimed, this cannot simply be assumed.

The *Robertson* decision also states that any inherent anticipation must be inevitable:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Citing *Continental Can co. v. Monsanto Co.* (supra); *In re Oelrich*, 666 F2d 578, 212 USPQ 323 (CCPA 1981).

The *Oelrich* case cited above is instructive in this regard. Oelrich's claim is directed to a control apparatus for moving low inertia steering fins on guided missiles. The claims required that the signal generated have a carrier frequency that is greater than the maximum dynamic command signal frequency and less than the minimum system resonant frequency. The evidence of record showed that the range of carrier frequency inherently disclosed in a prior art system overlapped that that might be used in the claimed system. The CCPA stated that that was not sufficient, because the teaching in the art would not inevitably result in the frequency associated with the claims.

A similar result was reached in *Glaxo Inc. v. Novopharm Ltd.*, 52 F3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995), where a polymorphic form of Zantac® (Form 2) was held not anticipated by examples describing the preparation of another form (Form 1) which were shown to occasionally yield Form 2. The prior art, the Court held, again, must inevitably result in the claimed subject matter.

Here, there is no showing that the claimed rodents would inevitably result from the procedure outlined by Kern.

The facts in this case are dissimilar from those of the cases cited by the Office as there is no actual product in the art for purposes of comparison. In *Ex parte Phillips*, 28 USPQ2d 1302 (BPAI 1993) the issue was obviousness (not anticipation) of a claimed monoclonal antibody over a monoclonal antibody that had actually been prepared and existed in the art for comparison. In *re Best*, 195 USPQ 430 (CCPA 1977) the claim was to a process for making zeolite catalysts and products thereof. The prior art process actually existed and gave results that could be compared.

Finally, in *Ex parte Gray*, 10 USPQ2d 1922 (BPAI 1989) claims were drawn to human β NGF prepared recombinantly. The issue there was whether the recombinantly produced protein was or was not identical to the purified protein that already existed and had been made in the art. Thus, in every case, there was an actual physical embodiment that could be compared, and these cases are not germane to a purely prophetic disclosure. The issue here is whether the prophecy of Kern would inevitably result in the rodents claimed herein.

For these reasons, it is believed that claims 1-3 are in a position for allowance and that claims 19 and 20 may be rejoined. Should any issues remain that might be resolved by phone, a telephone call to the undersigned is respectfully requested. Passage of these claims to issue is respectfully requested as well.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **docket No. 312762004400**.

Respectfully submitted,

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